REMARKS

In the office action, the Examiner withdrew the restriction requirement, maintained the species election requirement, raised anticipation rejections under 35 U.S.C. §102(b), and raised obviousness rejections under 35 U.S.C. §103(a).

Each rejection is addressed separately below. In view of the claim amendments noted above and the remarks presented below, applicants respectfully request reconsideration of the merits of this application.

A petition for a two-month extension of time accompanies this response so that the response will be deemed to have been timely filed. If any other extension of time is required in this or any subsequent response, please consider this to be a petition for the appropriate extension and a request to charge the petition fee to the Deposit Account No. 17-0055. No other fee is believed to be due in connection with this response. However, if any fee is due in this or any subsequent response, please charge the fee to the same Deposit Account No. 17-0055.

IN THE CLAIMS

Claims 2, 5-6, 12, 14, 16, 17, and 20 have been amended herein. Claims 1, 9-11, 15, and 21-22 have been cancelled. Claims 24-35 are newly added. Claim 4 has been withdrawn and new claim 27 reads on withdrawn subject matter.

§102 REJECTIONS

1. Anticipation rejection based on Draber et al.

Claims 1-3, 5-7, 9-10, 14-17, and 21-23 have been rejected as being anticipated by Draber et al., Journal of Immunological Methods, 181:37-43, 1995 (Draber). The Examiner contends that Draber teaches the stabilization of antibodies using trehalose via freeze-dried preparation of antibodies. Applicants submit that this rejection has been overcome by the appropriate amendments to the claims.

Specifically, claim 1 has been cancelled and claim 14 has been amended to recite exposure to steam at a binding-activity-destroying temperature. Support for this amendment can be found, for example, at line 16 of paragraph [00011] and line 16 of paragraph [00023] of the specification. In view the cancellation of claim 1, claim 14 has also been rewritten in

independent form. Draber does not teach treating a protein-saccharide composition with steam at a binding-activity-destroying temperature. Accordingly, as amended, claim 14 and dependent claims 2, 3, 5-8, 12, 13, 16-20, and 23 are not anticipated by Draber.

Regarding new claims 24-35, they recite providing and exposing a composition to a binding-activity-destroying temperature wherein the composition is formed by mixing and drying a saccharide and an egg containing an antibody produced therein (e.g., by spray dry as described in the specification). Draber does not teach this and thus does not anticipate new claims 24-35.

Accordingly, Applicants submit that the anticipation rejection based on Draber has been overcome and withdrawal of the rejection is requested.

2. Anticipation rejection based on Andya et al.

As an initial matter, applicants note that while section 3 on page 3 of the office action cited Draber et al., it seems that the Examiner intended to cite Andya et al., Pharmaceutical Research, 16:350-358, 1999 (Andya). For efficiency, applicants respond to the rejection as if it were raised over Andya.

Claims 1-3, 5-7, 9-10, 13, 14-17, and 21-23 have been rejected as being anticipated by Andya. The Examiner contends that Andya teaches a method of stabilizing sprayed dried protein using trehalose. Applicants submit that this rejection has been overcome by the appropriate amendments to the claims.

As discussed above, claim 1 has been cancelled and claim 14 has been amended to recite exposure to steam at a binding-activity-destroying temperature. Andya does not teach treating a protein-saccharide composition with steam at a binding-activity-destroying temperature. Accordingly, as amended, the claims at issue are not anticipated by Andya.

Regarding new claims 24-35, they recite providing and exposing a composition to a binding-activity-destroying temperature wherein the composition is formed by mixing and drying a saccharide and an egg containing an antibody produced therein (e.g., by spray dry as described in the specification). Andya does not teach this and thus does not anticipate new claims 24-35.

Accordingly, Applicants submit that the anticipation rejection based on Andya has been overcome and withdrawal of the rejection is requested.

§103 REJECTIONS

As an initial matter, applicants note while the first paragraph in section 4 on page 4 of the office action cites Wantanbe et al., it seems that the Examiner intended to cite Andya (discussed above) instead. For efficiency, applicants respond to the rejection as if Andya was cited.

Claims 1-3 and 5-23 have been rejected as obvious over U.S. Patent No. 6,213,930 to Cook et al. (Cook) in view of Draber (discussed above) or Andya (discussed above). Applicants submit that this rejection has been overcome by the amendments to the claims.

Specifically, claim 1 has been cancelled and claim 14 has been amended to recite exposure to "steam at a binding-activity-destroying temperature." Applicants submit that as amended, the claims at issue are not obvious over Cook in view of Draber or Andya.

1. Claim 14 and dependent claims thereof are not obvious.

The amended claim 14 contains two steps. The first step provides a composition comprising a protein (having a binding activity) and a saccharide formed by mixing and drying the protein and the saccharide together (e.g., by spray dry as described in the specification). The second step involves exposing the above dried mixture to steam at a binding-activity-destroying temperature. As provided in the specification, by mixing and drying with a saccharide, the binding activity of the protein is protected when the dried composition is subsequently exposed to a high temperature. It is not obvious and in fact counterintuitive to expose the dried mixture to a high temperature in the presence of steam because steam may dissolve the saccharide and thereby destroy the protective structure formed between the saccharide and the protein that protects the protein's binding activity.

Draber teaches mixing an antibody and trehalose and freeze-drying the mixture (page 38, the paragraph bridging the left and right columns). Draber showed that the activity of the antibody is protected in the dried mixture when stored at 50°C for 14 days (Fig. 3 and related text). However, the exposure of the dried mixture to 50°C was not in the presence of steam. Nothing in Draber suggests, either explicitly or implicitly, that the activity of the antibody in the dried mixture can still be protected if steam is present along with a high temperature given that trehalose can be dissolved under such conditions and thereby destroy the protective structure formed between trehalose and the antibody that protects the antibody's binding activity.

Andya teaches mixing an antibody and trehalose and spray-drying the mixture (page 351, left column under "Formulation" and "Spray-Drying"). Andya does not even disclose subsequently exposing the dried mixture to a high temperature, much less in the presence of steam (the second step of claim 14). Nothing in Andya suggests, either explicitly or implicitly, that the activity of the antibody in the dried mixture can be protected if subsequently exposed to a high temperature, much less in the presence of steam given that trehalose can be dissolved under such conditions and thereby destroy the protective structure formed between trehalose and the antibody that protects the antibody's binding activity.

For the above reasons, claim 14 and dependent claims 2, 3, 5-8, 12, 13, 16-20, and 23 are not obvious over Cook in view of Draber to Andya.

2. New claims 24-35 are not obvious.

New claim 24 contains two steps. The first step provides a composition formed by mixing and drying a saccharide and an egg containing an antibody produced therein (e.g., by spray dry as described in the specification). The second step involves exposing the above dried mixture to a binding-activity-destroying temperature wherein the binding activity of the antibody is protected from thermal stress.

Draber teaches mixing an antibody provided in an ascitic fluid and trehalose and freeze-drying the mixture (page 38, the paragraph bridging the left and right columns). Draber showed that the activity of the antibody is protected in the dried mixture when stored at 50°C for 14 days (Fig. 3 and related text). Andya teaches mixing an antibody and trehalose and spray-drying the mixture (page 351, left column under "Formulation" and "Spray-Drying"). Andya does not even disclose the second step of new claim 24, i.e., subsequently exposing the dried mixture to a high temperature.

Unlike the ascitic fluid in Draber and the purified antibody in Andya, the egg recited in the new claims contains a high level of fat. It is well known in the art that fat transmits heat rapidly and this is why fat is chosen for deep frying applications in the food industry to prepare fried foods such as savory snacks, fried chicken, fried fish, french fries, and the like (see U.S. patent 5597605, column 7, line 67 to column 8, line 6). Therefore, even assuming for the sake of argument that one skilled in the art would recognize from Draber and Andya that mixing and

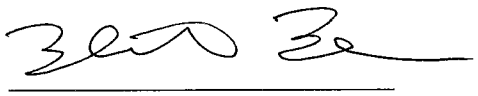
drying an antibody with trehalose would protect the antibody from future thermal stress, it is not obvious and in fact counterintuitive to include a high level of fat in the mixture because fat would transmit heat rapidly and thus defeat the purpose of protecting the antibody from thermal stress. As an aside, fat in a large quantity may also interfere with the formation of the protective structure between trehalose and the antibody. At the very least, the above problems in connection with the high fat level in eggs would inject sufficient doubt into the mind of a skilled artisan so that the skilled artisan would not be able to conclude with reasonable certainty that mixing and drying an egg with a saccharide would be able to effectively protect an antibody in the egg from thermal stress.

For the above reasons, new claims 24-35 are not obvious over Cook in view of Draber to Andya.

SUMMARY

Having addressed each rejection raised by the Examiner through claim amendments and remarks noted above, the claims at issue as amended are believed to be in condition for allowance and a Notice of Allowance is respectfully requested. Should any issues remain outstanding, the Examiner is invited to contact the undersigned at the telephone number appearing below if such would advance the prosecution of this application.

Respectfully submitted,



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